IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

ALISSA DREGER,

Plaintiff,

vs.

Case No. 2:20-cv-3814

Judge Michael H. Watson

Magistrate Judge Elizabeth P. Deavers

KLS MARTIN, L.P.,

Defendant.

ORDER and MEMORANDUM DECISION

This matter came before the Court on June 2, 2022, for a telephonic status conference. Counsel for all parties appeared and participated in the conference.

In its April 11, 2022 Opinion and Order, (ECF No. 47), the Court set forth the details of the parties' discovery dispute and ordered the parties to confer regarding the regarding the conditions for an inspection of the rib fixation plate at issue in this case (the "Explanted Device"). As the attached letter briefing reflects, the parties reached agreement with respect to many conditions but remained at impasse with respect to two issues. In addition, Plaintiff has proposed another condition on May 6, 2022. Having thoroughly reviewed the parties' letter briefing and appropriate case law, the Court renders the following decisions regarding the parties' remaining issues.

A. Plaintiff's Second Condition – Inspection to Occur in the Continental United States

Plaintiff wants KLS to conduct its inspection of the Explanted Device within the continental United States. KLS explains that it "is unwilling to agree to this condition, as it is contrary to

KLS' policies relating to explanted medical devices, industry standards, and regulatory reporting requirements imposed by the United States Food and Drug Administration ("FDA")."[1] (Def. Br. at p. 2.) KLS further elaborates its position as follows:

> All of KLS' explanted titanium or titanium alloy medical devices are evaluated by the device manufacturer, Karl Leibinger Medizintechnik GmbH ("KLM"), at its state-of-the-art laboratory facilities, where the devices are inspected by KLM's expert engineers, whose job duties include the evaluation of explanted medical devices through the use of high-powered stereomicroscopy and in some cases high-resolution scanning electron microscopy and approved non-invasive and non-destructive testing only. This has been KLS' standard protocol since KLS was founded in 1993. KLM's laboratory facilities and expert engineers are located in Germany. The laboratory facilities and much of the specialized equipment located therein (e.g., industrial laboratory microscopes and related computer equipment) are not portable. KLM's laboratory facilities are routinely inspected and approved by the FDA and other regulatory agencies and are subjected to the highest standards. To be clear, the manufacturer's evaluation of explanted medical devices at KLM's lab is regulated and audited by the FDA and is subject to United States law.

(Def. Br. at p. 3.)

Plaintiff counters that "KLS continues to advance the entirely meritless argument that applicable law requires its inspections of the rib plate to occur in Germany. . . . Needless to say, the Court has already soundly rejected this argument." (Pl. Br. at p. 1.) Plaintiff contends that KLS offers no authority to support its argument that KLS always conducts its inspections of explanted devices in Germany. She maintains that KLA offers "no real reason why it could not inspect the plate – which will essentially consist of looking at it under a microscope – in the

[1] Citing 21 C.F.R. §§ 803.50 and 803.52 (requiring KLS to report to the FDA information that is "reasonably known" to KLS, including "[a]ny information that [KLS] can obtain by analysis, testing, or other evaluation of the device," or to provide an explanation in the event that no evaluation was performed).

United States . . . ." (Pl. Br. at p.2.) Plaintiff insists that KLS "ominously suggested in its motion to compel that,

> any subpoena to Karl Leibinger Medizintechnik would have to comply with the Hague Convention's onerous rules for service of a foreign subpoena. . . . This would present an insurmountable issue should KLM fail to return the plate. Obviously, it is imperative that Plaintiff be able to use the plate at trial and show it to the jury. Its loss would irreparably harm Plaintiff's ability to put on her case.

(Pl. Br. at p. 2.)

The Court concludes that KLS is entitled to conduct an evaluation of the Explanted device at the facility of its choice with the specialized facilities, equipment, and expert engineers at Karl Leibinger Medizintechnik in Germany ("KLM"). At the outset, the Court notes that it has not, as Plaintiff suggests, "soundly rejected" the argument that applicable law requires the inspection of the Explanted Device in Germany. In its April 11, 2022 Opinion and Order, the Court merely concluded that KLS had no legal right to permanent possession of the rib plate and said nothing as to the conditions under which it could be inspected. (*See* ECF No. 47 at pp. 5-6.) The Court did **not** find that KLS had no obligations under the FDA to report information that is reasonably known, including information from evaluation of the Explanted Device *once it came into its possession for inspection*. Indeed, the regulations cited by KLS plainly require it to comply with the rules promulgated by the FDA.

Plaintiff's concerns about KLS not having possession, custody or control over the Explanted Device, would have to comply with the Hague Convention, and the potential that she would not have the device for trial are allayed for several reasons. First, compliance with the Hague Convention is not required for KLM to return the Explanted Device. Moreover, KLS has stipulated that it will promptly return the Explanted Device to Plaintiff's counsel upon conclusion of its expert evaluation. Although KLS does not have possession, custody and control over

documents and things in KLM's possession, KLS routinely returns explanted devices to KLM for a manufacture's evaluation in Germany, and KLM routinely returns the explanted medical devices to KLS. According to KLS, in almost 30 years of routine shipments between it and KLM, no device has ever been lost. Plaintiff's suggestion that she would be harmed if she did not have the Explanted Device for trial is purely speculative at this point.

B. KLS to Produce Expert for Deposition in Columbus, Ohio

The Court agrees with Plaintiff that this issue is premature. The parties are **DIRECTED** to contact the Court after KLS designates an expert if the matter is still at issue.

C. Observation of Testing

Plaintiff now believes it is reasonable for her expert and/or counsel to observe the testing of the Explanted Device. But the cases she cites either refer to instances in which the court permitted the opposing party to observe *destructive* testing or the court had little to no analysis because the parties had no objection. Here, there is a clear distinction because this case involving non-destructive testing.

Further, as KLS points out, as with any other factual investigation in a lawsuit, unless and until KLS elects to use information from KLM's manufacturer's evaluation of the Explanted Device as evidence in this case, KLS is entitled to protect the work product generated by the inspection, along with the identities of, and facts known or opinions held by, KLS' consulting experts.

The parties' request to memorialize their stipulation is **GRANTED**. KLS will promptly return the Explanted Device to Plaintiff's counsel as soon as KLS's expert has finished examining it.

Finally, the parties are **DIRECTED** to file a Motion directed at the case schedule as soon as practicable. The Court encourages the parties to cooperate and arrive at an agreed schedule.

IT IS SO ORDERED.

/s/ *Elizabeth A. Preston Deavers*
ELIZABETH A. PRESTON DEAVERS
UNITED STATES MAGISTRATE JUDGE

DATED: June 6, 2022